

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
27 May 2004 (27.05.2004)

PCT

(10) International Publication Number
WO 2004/043266 A2

(51) International Patent Classification⁷: **A61B 17/00**

(21) International Application Number:
PCT/US2003/035998

(22) International Filing Date:
7 November 2003 (07.11.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/424,491 7 November 2002 (07.11.2002) US

(71) Applicant (for all designated States except US): NMT
MEDICAL, INC. [US/US]; 27 Wormwood Street,
Boston, MA 02210 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): OPOLSKI, Steven,
W. [US/US]; 330 Fiske Street, Carlisle, MA 01741 (US).

(74) Agents: DIENER, Michael et al.; Hale and Dorr LLP, 60
State Street, Boston, MA 02109 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE,
GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR,
KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK,
MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT,
RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR,
TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

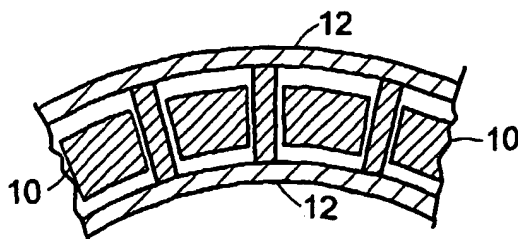
(84) Designated States (regional): ARIPO patent (BW, GH,
GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE,
SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished
upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: PATENT FORAMEN OVALE (PFO) CLOSURE WITH MAGNETIC FORCE



(57) Abstract: Magnetic force, preferably with one or more per-
manent magnets, is used to hold together flaps of tissue inside the
body, particularly flaps of a PFO. A device or magnets within a de-
vice can be retrieved such that no permanent implant is left behind.

WO 2004/043266 A2

PATENT FORAMEN OVALE (PFO) CLOSURE WITH MAGNETIC FORCE

Cross-Reference to Related Application

5

This application claims priority from provisional application serial no. 60/424,491, filed November 7, 2002, which is incorporated herein by reference.

Background of the Invention

10

A patent foramen ovale (PFO) is a persistent, one-way, typically flap-like opening in a wall between the right atrium and the left atrium of the heart. Left atrial (LA) pressure is typically higher than right atrial (RA) pressure, so the flap typically stays closed. Under certain conditions, however, RA pressure can exceed LA
15 pressure, creating the possibility for right to left shunting that can allow blood clots to enter systemic circulation. In utero, the foramen ovale serves as a physiologic conduit for right-to-left shunting. After birth, with the establishment of pulmonary circulation, the increased left atrial blood flow and pressure results in functional closure of the
20 closure of the two overlapping layers of tissue, referred to as septum primum and septum secundum.

Studies have confirmed a strong association between the presence of a PFO and a risk for paradoxical embolism or stroke. In addition, there is evidence that patients with PFO and paradoxical embolism are at increased risk for future, recurrent
25 cerebrovascular events.

The presence of a PFO has no therapeutic consequence in otherwise healthy adults. In contrast, patients suffering a stroke or TIA in the presence of a PFO and without another cause of ischemic stroke are considered for prophylactic medical therapy to reduce the risk of a recurrent embolic event. These patients are commonly
30 treated with oral anticoagulants, which have the potential for adverse side effects, such as hemorrhaging, hematoma, and interactions with a variety of other drugs. In certain cases, such as when anticoagulation is contraindicated, surgery may be used to close a PFO. To suture a PFO closed requires attachment of septum secundum to septum

primum with either a continuous or interrupted stitch, which is a common way a surgeon shuts the PFO under direct visualization.

Nonsurgical closure of PFOs has become possible with the advent of umbrella devices and a variety of other similar mechanical closure designs, developed initially
5 for percutaneous closure of atrial septal defects (ASD). These devices allow patients to avoid the potential side effects often associated with anticoagulation therapies.

Summary of the Invention

The present invention includes the use of magnetic force, preferably with one or more permanent (non-electromagnetic) magnets, to hold together flaps of tissue
10 inside the body, particularly a PFO. Magnets, such as rare earth magnets, that develop high attractive forces when separated with a material or air gap are preferably used. It can be preferable for a number of magnets to be provided in a conduit to provide some flexibility. If desired, after a period of time, such as a few weeks, the entire device or the magnets within the device can be retrieved such that no permanent implant is left
15 behind.

The invention also includes methods for using magnetic force, including deploying a magnet on one side of a region to be treated, deploying a magnetically attractive piece that is attractive to the magnet (and which might or might not be a magnet), with the magnet and magnetically attractive piece part of a device such as a
20 septal occluder or a PFO closure device.

The use of magnets with a sheath or container adapted for in-growth can promote healing and potentially allow the PFO to close, preferably with a very small device in terms of diameter and metal mass. Other features will become apparent from the drawings, description, and claims.

25

Brief Description of Drawings

Fig. 1 is a cross-sectional view of a conduit with magnets.

Fig. 2 is a side view of components on either side of a PFO where one or both components include magnets.

Fig. 3 is a top view of components on either side of a PFO where one or both components include magnets.

Fig. 4 shows a device with magnets at the end of petals, in a catheter for deployment.

5 Fig. 5 shows a device with petals as deployed.

Fig. 6 shows a device similar to that in Fig. 4, in a catheter for deployment.

Detailed Description

Referring to Fig. 1, one or more magnets can be used to provide magnetic force with sufficient attractive force to hold together the flaps of a PFO, and preferably to cause regrowth between the flaps, but not too much to create tissue damage. To provide a locally strong magnetic field without bulky weight, it is desirable to use small, rare earth magnets, although other magnets could be used. While magnets are typically rigid, some flexibility can be provided in the magnetic structure by using a group of magnets, such as a short length of magnets 10, in a flexible conduit 12. The magnets can be connected together, such as with a wire, or can be separated by walls within the conduit, or can even be loose within a conduit. A conduit for holding magnets, or selected portions thereof, can be made of bioresorbable material, or can be made with materials, sizes, and/or coatings that promote or hinder in-growth, depending on the way in which it is being used. Examples of materials that can be used and that promote in-growth include vascular graft material, such as knitted or woven polyester, expanded PTFE, polyurethane, or polyvinyl alcohol (PVA).

Referring also to Fig. 2, two magnets, or preferably sets of magnets 14, 16, with each set in a conduit such as that shown generally in Fig. 1, can be provided on either side of the PFO as defined by flaps 18, 20 (septum secundum and septum primum) with a connector 22, such as a wire or a polymer fabric scaffold. The magnetically attractive force forms a line of contact along the flap of the PFO. Alternatively, a magnet can be used on one side of the PFO with only a magnetically attractive material, such as a metal, on the other side of the PFO. The conduit and magnets are typically inserted through the use of a catheter.

The magnets can be left in permanently, in which case it would be desirable to promote in-growth around the conduit. One drawback to the use of magnets in the body on a permanent basis, however, is that their presence would limit the use of MRI (magnetic resonance imaging).

5 By making the magnets retrievable, MRI could be used later for a patient that had magnets removed. A conduit (such as that shown in Fig. 1) into which magnets are placed is designed to limit or restrict the amount of tissue in-growth to the tube. This limitation of in-growth can be effected by the selection of mesh size, choice of materials, or use of a coating on the conduit. The magnets can alternatively be
10 provided in an inner sheath within an outer sheath that is made of a material and/or with a design to encourage tissue in-growth into and around the sheath. This means that the tissue can grow together around the sheath. A subsequent procedure is used to pull the magnets and inner sheath from the outer sheath by either sliding the inner sheath out from the outer sheath. Alternatively, the outer sheath can be made
15 bioresorbable, and the inner sheath is removed before it has been resorbed.

Referring to Fig. 4, a portion of a device 40 is shown in a catheter 42. The device has a number of wires 44 (shown here as four in number), connected at a hub 46. At the end of wires 44 are magnets 48, and against the magnets is a fabric 50. The magnets can be oriented to have a repulsive force. Referring also to Fig. 5, as
20 deployed, the repulsive force of the magnets causes the wires connected to the fabric 50 to spread out against one side of the PFO. A second device can be provided each with magnets 52 against a fabric 54, with magnets 52 having an orientation that causes an attractive force to magnets 48. As a result, magnets 52 and 48 are attracted to each other to help hold the PFO closed. The wires can be made of a shape memory
25 material, such as nitinol.

Fig. 6 shows a device similar to that shown in Fig. 4 in which the device is half folded on itself to reduce the profile of the device within the catheter. A fabric can be used in this case if desired.

Other methods can be used whereby petals or other structures are created,
30 taking advantage of the attractive and repulsive forces of magnets.

The strength of the magnets and the size and shape of the magnets and conduit can be determined experimentally, taking into consideration the gap between the materials on either side of the PFO.

Accordingly, the present invention has been described with respect to
5 exemplary embodiments of the present invention. It should be appreciated, though, that the present invention is defined by the following claims. Modifications or changes may be made to the exemplary embodiments of the present invention without departing from the inventive concepts contained herein or the scope of the claims.

What is claimed:

Claims

1. A method comprising using magnetic force to hold together septum primum and septum secundum of a patent foramen ovale (PFO), including providing on one side of the PFO a first magnet and on the other side of the PFO a block such
5 that the block and the first magnet have a magnetically attractive force to compress septum primum and septum secundum between them.
2. The method of claim 1, wherein one or more magnets are introduced to one side of a PFO through a catheter.
3. The method of claim 1, wherein the block is a second magnet.
- 10 4. The method of claim 3, wherein the first and second magnets are held in respective first and second sheaths.
5. The method of claim 4, wherein the first and second sheaths are coupled together.
6. The method of claim 4, wherein the first and second magnets are
15 coupled together with a flexible material that passes between septum primum and septum secundum.
7. The method of claim 4, wherein the first magnet is one of a plurality of magnets within a conduit to produce a flexible magnetic structure on one side of the PFO.
- 20 8. The method of claim 7, wherein the plurality of magnets within a conduit and a structure including the second magnet are coupled together with a flexible material that passes between septum primum and septum secundum.
9. The method of claim 1, wherein the one side of the PFO has a plurality of magnets.
- 25 10. The method of claim 1, including providing one or more magnets on the one side of a PFO, and further comprising removing the one or more magnets after septum primum and septum secundum have started in-growth around a conduit for holding the magnets.

11. The method of claim 10, wherein the magnets are provided in a conduit adapted to discourages tissue in-growth.
12. The method of claim 1, including providing one or more magnets on one side of a PFO and leaving the one or more magnets in the body indefinitely.
- 5 13. The method of claim 1, including providing one or more magnets on one side of a PFO, wherein at least one magnet is a distal end of a spoke of a device with a hub and at least two spokes, with the proximal end of the spokes at the hub.
14. The method of claim 1, wherein one or more magnets are provided to a side of the PFO in an inner sheath within an outer sheath, the inner sheath being
10 removable from the outer sheath.
15. The method of claim 14, wherein the outer sheath is adapted to encourage tissue in-growth.
16. The method of claim 14, wherein the outer sheath is made of a bioresorbable material.
- 15 17. The method of claim 16, wherein the one or more magnets are introduced in a first procedure, and the inner sheath is removed in a second procedure.
18. A patent foramen ovale (PFO) closure device comprising a first magnet and a block, the block and the first magnet having an attractive force, the device being deployable in a living body such that the first magnet and the block are on opposite
20 sides of the PFO, and use magnetic force to hold together septum primum and septum secundum of the PFO.
19. The device of claim 18, wherein the block includes a second magnet.
20. The device of claim 19, wherein the first and second magnets are held in respective first and second sheaths.
- 25 21. The device of claim 20, wherein the first and second sheaths are coupled together.
22. The device of claim 21, wherein the sheaths are coupled with a connector adapted to extend from one side of a PFO to another between septum primum and septum secundum.

23. The device of claim 20, wherein the first and second sheaths are within an outer sheath.

24. The device of claim 23, wherein the outer sheath is adapted to encourage tissue in-growth.

5 25. The device of claim 23, wherein the outer sheath is made of a bioresorbable material.

26. The device of claim 19, wherein the device includes a plurality of magnets in a conduit to form a flexible magnetic structure.

10 27. The device of claim 18, further comprising a catheter for delivering the closure device, the closure device being movable from a delivery position in which the device can be provided within the catheter to a deployed position in the living body.

28. The device of claim 18, wherein the device has an outer container and an inner container for holding one or more magnets, the inner container being removable from the outer container.

15 29. The device of claim 28, wherein the outer sheath is adapted to encourage in-growth, and the inner container is adapted to inhibit in-growth.

30. The device of claim 29, wherein the inner and outer sheaths are adapted to inhibit and encourage in-growth by the use of different materials.

1/1

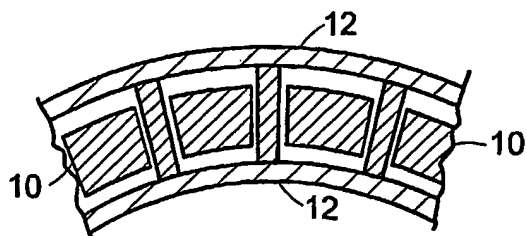


FIG. 1

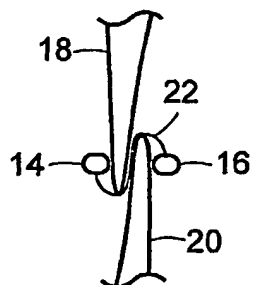


FIG. 2

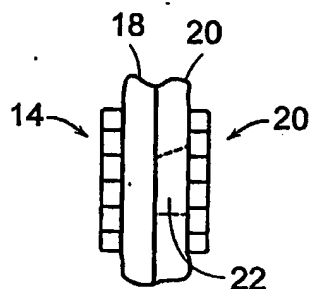


FIG. 3

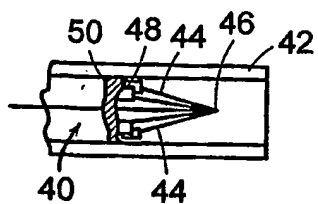


FIG. 4

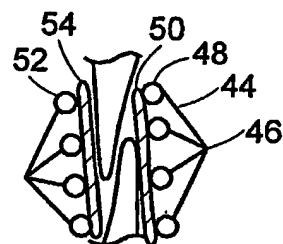


FIG. 5

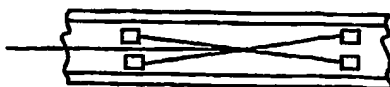


FIG. 6